K100913

5. 510(k) Summary

MAY 2 6 2010

Submitter: Midmark Diagnostics Group

Trade Names: IQvitals and IQvitals System

Common Name: Patient Physiological Monitor (without arrhythmia detection or alarms)

Classification Name: Non-invasive Blood Pressure Measurement System

Classification Regulation: 21 CFR 870.1130

Product Code: DXN

Device Description

The IQvitals and IQvitals System are patient monitors intended to be used by clinicians and qualified medical personnel for spot check monitoring of non-invasive blood pressure (NIBP), pulse oximetry (SpO_2), temperature and for the IQvitals device, weight.

Patient Record information, such as height, respiration rate and pain level, can be manually entered by clinicians via the user interface.

Technology Comparison

The IQvitals and IQvitals System utilizes the same or similar technology for each parameter as utilized by the predicate device. There are no different technologies between the IQvitals and IQvitals System and the predicate Well@Home System.

The legally marketed predicate device is the Well@Home System (K040012).

Intended Use

The IQvitals and IQvitals System is intended to be used by clinicians and medically qualified personnel for measuring adult and pediatric patients for noninvasive blood pressure, pulse rate, noninvasive functional oxygen saturation of arterial hemoglobin (SpO_2), temperature and weight.

Patient information such as name, age, height, pain score etc. can be entered manually.

Performance Testing

The IQvitals and IQvitals System was tested in accordance with requirements and procedures, and test results indicated that the device complies with the predetermined requirements.

The following non-clinical areas were thoroughly tested or evaluated to both standards and the predicate:

Non Invasive Blood Pressure
Temperature
SpO2
Pulse Rate
Display
Electrical
Environmental
Software
Biocompatibility

Conclusion

Based upon a comparison of devices and performance testing results, the IQvitals and IQvitals System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 26 2010

Brentwood Medical Technology Corp.
c/o Mr. Greg Holland
Regulatory Specialists, Inc.
3722 Ave. Sausalito
Irvine, CA 92606

Re: K100913
Trade/Device Name: IQ Vitals and IQ Vitals System
Regulatory Number: 21 CFR 870.1130
Regulation Name: Non-invasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: DXN
Dated: May 12, 2010
Received: May 13, 2010

Dear Mr. Holland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

Indications for Use

510(k) Number: K100913

Device Name: **IQvitals and IQvitals System**

Indications for Use:

The IQvitals and IQvitals System is intended to be used by clinicians and medically qualified personnel for measuring adult and pediatric patients for noninvasive blood pressure, pulse rate, noninvasive functional oxygen saturation of arterial hemoglobin (SpO_2), temperature and weight.

Patient information such as name, age, height, pain score etc. can be entered manually.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K100913